August 2003 Volume 1, Issue 1

RCQ REVIEW

Newsletter of the Office of Regulatory Compliance and Quality
United States Army Medical Research Materiel Command

INSIDE THIS ISSUE:

SPECIAL POINTS OF INTEREST:

* Meet the RCQ Team
* RCQ Organizational Chart
* HIPAA Highlights
* PRIM&R

MESSAGE FROM THE DEPUTY, REGULATORY COMPLIANCE AND QUALITY

Message from the Deputy, Regulatory Compliance and Quality...

COL Laura R. Brosch
Deputy, RCQ

Greetings from the Office of Regulatory Compliance and Quality (RCQ) at the United States Army Medical Research and Materiel Command (USAMRMC). With this inaugural newsletter we want to introduce ourselves and explain what we do. Our office is charged with a variety of oversight and policy missions for USAMRMC. Our goal is to provide members of MRMC and our MRMC-funded extramural investigators with the regulatory information they need to conduct studies that meet the national and Department of Defense (DOD) regulatory standards. Our office is working to improve regulatory processes within the command. Our goal is to provide you with timely, accurate and comprehensive responses to your inquires. We plan to publish this newsletter quarterly to provide you with regulatory and quality assurance updates.

Over the next 18 months our staff assistance teams will be scheduling visits with the USAMRMC subordinate commands to provide on-site review and assistance. As the regulatory environment becomes increasingly complex we will strive to provide you with the information you need today to meet your mission requirements in full compliance and the regulatory guidance that will help you plan for the future.

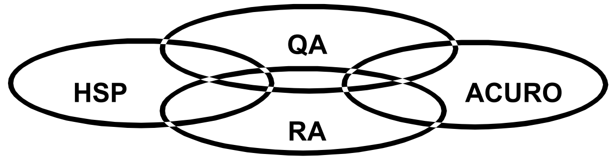
Please feel free to contact me if you have any questions, concerns, or suggestions at Laura.Brosch@det.amedd.army.mil.

LAURA R. BROSCH
COL, AN
Deputy for Regulatory Compliance and Quality

What is RCQ?

The RCQ Front Office Staff
(From Left to Right) Linda Reese, Shannon Lertora, Julie Burns-Feaga

Office of Regulatory Compliance and Quality



Mission: To ensure the regulatory compliance and quality of all USAMRMC conducted or managed medical research and development activities.

Objective 1. Be the customer's choice for assistance with ensuring regulatory compliance and quality assurance of all medical research and development activities conducted or managed by the USAMRMC.

Objective 2. Ensure that all our RCQ business practices are flexible, dynamic, and agile in order to effectively and efficiently respond to and plan for the regulatory compliance and quality assurance requirements of USAMRMC medical research and development activities in support of traditional and non-traditional Defense mission areas.

Objective 3. Keep the USAMRMC people who conduct, manage, and review medical research and development activities competent and relevant in all aspects of the regulatory compliance and quality assurance requirements of their activities.

See the Office of Regulatory and Quality organization chart on page 7.

Meet the RCQ Branches

Human Subjects Protection

HSP

In January 2003, the Human Subjects Protection Branch (HSP) split into two separate subdivisions: the Research Administrative Support Branch (RAS) and the Human Subjects Protection Review Branch (HSP Review Branch). Together these branches make up the Human Subjects Protection Division of RCQ.

Suzanne Pursley-Crotteau, PhD, RN is the Chief of the RAS Branch. She came to RCQ in 2001 and is currently also the Human Subject Research Review Board (HSRRB) Administrator. Previously, she was an Associate Professor in the Mental-Health Psychiatric Nursing Department at the Medical College of Georgia (Augusta, Georgia).

The RAS Branch is responsible for the life-cycle man-

The Research Administrative Support Branch
(From Left to Right) Back Row: Suzanne Pursley-Crotteau, Thelma Condon, Catherine Smith, Michelle Von Reichenbach
Front Row: George Dodge, Jodi Bennett, Jessica Banks, Christa Phillips (Not Pictured Kelly Ashley)

(Continued on page 3)

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agement of over 600 HSRRB protocol submissions per year. Life-cycle management includes review of Program and Broad Agency Announcements (BAA) for both regulatory clarity and specificity, triage of all proposals into RCQ, triage of all protocols for Human Use Review, and the request and receipt of paper as well as electronic protocol documents necessary for an ethical review. In addition, the RAS Branch is accountable for processing continuing reviews, adverse events, and final study reports at the end of the research. This branch closes out each protocol file when the research is finished and the award is complete. Lastly, the RAS branch determines when a protocol is exempt from the requirements for human use review. The RAS has reviewed more than 400 Exempt protocols over the past year. The HSRRB issues single-project and multiple-project Assurances of Compliance with DOD regulations for the protection of human subjects. Dr. Pursley-Crotteau and the RAS Branch will assume responsibility for the issuance and oversight of these assurances.

Along with Dr. Pursley-Crotteau, eight other individuals help maintain the life-cycle management process. They are:

- Ms. Jodi Bennett – handles the production of the HSRRB Minutes and maintains the Human Use Committee (HUC)/Human Use Review Committee (HURC) minutes from the subordinate labs
- Ms. Thelma Condon – triages proposals and assistant agreements to all branches of RCQ
- Mr. George Dodge – manages the operational aspects of publishing and delivering the read-ahead packets for HSRRB members and sets up HSRRB meetings
- Ms. Catherine Smith – reviews the Exempt protocols
- Ms. Michelle von Reichenbach – point of contact for the triage of Human Use Protocols
- Ms. Kelly Ashley – student employee
- Ms. Jessica Banks – student employee
- Ms. Christa Phillips – student employee

All members of the RAS Branch are ready to assist both intramural and extramural customers with questions related to regulatory concerns and the HSRRB protocol life-cycle. Dr. Pursley-Crotteau is interested in knowing how the RAS team has been helpful and/or how they can improve their service to you. Feedback is requested via e-mail to Suzanne.Pursley-Crotteau@det.amedd.army.mil or HSRRB@det.amedd.army.mil.

Ms. Caryn Duchesneau is the Chief of the HSP Review Branch. She joined RCQ in December 1999. She also serves as the Vice Acting Chair of the HSRRB. Ms. Duchesneau previously worked in quality assurance and regulatory affairs for a pediatric vaccine manufacturer and is certified in Biopharmaceutical Regulatory Engineering.

The HSP Review Branch provides expert reviews to assist COL Laura R. Brosch, AN, Acting Chair of the HSRRB. This branch assists with the initial review and ongoing monitoring of over 1,200 active intramural and extramural protocols for which the HSRRB has first or second level oversight.

The Human Subjects Protection Review Branch
(From Left to Right) Back Row: Donna Ferrandino, Louise Pascal, Robin Dillner, Melanie Oringer, Tibor Tuzson, Maryann Pranulis, Inese Beitins
Front Row: Caryn Duchesneau, Andrea Kline, Peter Marshall, Diana Weld, Vern Jimmerson (Not Pictured Pat Dubill)

The HSP Review Branch now employs twelve Human Subjects Protection Scientists with a wide range of specialty expertise that includes behavioral research, exercise physiology, genetics, HIV research, Investigational New Drugs (INDs), medical devices, molecular biology, nutrition, and pediatrics. The HSP scientists provide informal and formal guidance to investigators on behalf of the Acting Chair of the HSRRB. Furthermore, these reviewers assist investigators with preparing documents for formal review by the Acting Chair or the full Board.

(Continued on page 4)

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The HSP Review Branch also participates in staff assistance visits to the intramural laboratories and often provides education and guidance to extramural researchers through participation in product line reviews and by speaking at other special events and meetings.

Over the past year, the HSP review staff played a central role in the preparation, review and approval of the contingency protocols for Force Health Protection that were available for use in the Global War on Terrorism. The staff is currently involved with continuous monitoring of these protocols on behalf of the HSRRB, which serves as the Institutional Review Board (IRB) of record.

Over the next few months the HSP Review Branch will be focusing on developing ways to better communicate HSRRB expectations by making website improvements, providing additional and updated guidance documents for investigators, and assisting with development of clear HSRRB policies.

In an effort to meet your specific needs, Ms. Duchesneau welcomes any feedback or suggestions from their customers on areas that are in need of clarification and ways that they can effectively communicate HSRRB policy as well as assisting with navigation through the HSRRB review process. She would like to challenge each of our customers to provide them with the top three things that the HSP Review Branch could do to help you. Feedback, to include topics that you would like to see in future newsletters, can be provided via email to Caryn.Duchesneau@det.amedd.army.mil or to HSRRB@det.amedd.army.mil.

Quality Assurance

QA

A message from Mary Burman, Branch Chief, Quality Assurance...

As we move forward during these rapidly changing times, communication is one key to our success as an organization. It is with great pleasure that the Quality Assurance Branch (QA) writes this first article to help open up and facilitate communication with all of you, our customers. Please feel free to let us know your questions and issues so we can maintain a dialog as we all take on new challenges and grow as an organization. Quality is integral to the success of our missions.

For those of you who are unfamiliar, the QA Branch of the Office of Regulatory Compliance and Quality (RCQ) is composed of the following individuals: Ms. Mary Burman, Chief; Ms. Lori Walton, QA Scientist; Ms. Brenda Meredith, QA Scientist; Ms. Carol Dzik, Secretary; and Ms. Maya Laws, Student Support. Our offices are located at Ft. Detrick in building 504XX. We welcome your visit.

The QA staff is currently engaged in Command Inspection Program visits to conduct an assessment of the Quality Programs and their components currently being implemented within the Major Subordinate Commands. This assessment is important to ensure that future efforts to rewrite the Command

The Quality Assurance Branch
(From Left to Right) Brenda Meredith, Mary Burman, Carol Dzik, and Maya Laws
(Not Pictured Lori Walton)

Quality Assurance regulation encompass the breath and scope of our quality programs within all the subordinate commands.

Licensing, Credentialing and Privileging has been in the spotlight and Ms. Brenda Meredith, with the help of the involved Subordinate Commands, has put a policy into place that addresses how United States Army Medical Research and Materiel Command

(Continued on page 5)

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(USAMRMC) handles these efforts. This policy will serve as a template for other United States Army Medical Command (MEDCOM) organizations that do not fall directly under Medical Treatment Facilities. Training for those organizations involved in the implementation of the policy is forthcoming. Thank you for all the support in these efforts to date. It takes a team effort to make an undertaking such as this one succeed.

A resource you may want to review is AR 5-1, Total Army Quality Management, dated 15 March 2002. The regulation emphasizes the Army's commitment to performance excellence through leadership and vision, mission and customer focus, employee empowerment and continuous improvement. The regulation can be found at the following web site:

http://www.usapa.army.mil/searchtitle_number_pubs.asp

As stated earlier, please dialog with us and let us know topic/issues you would like to hear about in future newsletters. One future for discussion will be the difference between Quality Assurance and Quality Control. Please contact Mary Burman at Mary.Burman@det.amedd.army.mil.

REGULATORY AFFAIRS

RA

Under the leadership of COL Jerry Pierson, MS, the Regulatory Affairs (RA) Branch provides regulatory oversight for the research and development of new drugs, devices, and biological products sponsored by the Department of the Army Surgeon General (TSG), serves as the point of contact with the Food and Drug Administration (FDA) for all TSG regulatory submissions and maintains the official files of regulatory submissions to the FDA. In addition, RA is responsible for conducting post-marketing surveillance for all TSG sponsored approved biological, drug or device products.

The Regulatory Affairs Branch
(From Left to Right) Back Row: Kathie Mantine, Micki Garey, COL Jerry Pierson
Front Row: Rebecca Moffatt

Assisting COL Pierson are Ms. Kathie Mantine, Ms. Rebecca Moffatt and Ms. Micki Garey.

Kathie Mantine works with representatives from the United States Army Medical Materiel Development Activity (USAMMDA) and Chemical, Biological Medical Systems (CBMS) to coordinate the submission of regulatory documents to the FDA. She reviews these documents prior to submission for completeness, accuracy and compliance with federal regulations. In addition, she assists human subject protection reviewers with TSG sponsored Investigational New Drug (IND) protocols and prepares post-marketing annual reports for The Surgeon General sponsored New Drug Application (NDA) products.

RA's administrative assistant, Rebecca Moffatt, drafts all correspondence that accompanies documents submitted to the FDA for the Office of The Surgeon General (OTSG) sponsored products and is responsible for processing documentation of all adverse events reported to the Human Subjects Research Review Board (HSRRB). Rebecca also assists in the maintenance of the regulatory submissions in both paper and electronic format.

Micki Garey, student employee, assists with data management as well as the filing, scanning and other activities that occur on a daily basis.

COL Pierson, who served with RCQ from 1997 to May of 2002, returned to Regulatory Affairs in August 2003 after an assignment as Pharmacy Consultant to 18th United States Army Medical Command (MEDCOM) in Korea. COL Pierson will continue with the program initiated by COL Isiah Harper to orchestrate the actions required to meet the FDA's post-marketing requirements for Pyridostigmine Bromide (PB). COL

Pierson is also a major proponent for all requirements involved with the use of investigational drugs for force health protection.

As a team, RA works together to accomplish their mission responsibly and successfully. For questions regarding RA contact COL Pierson at Jerry.Pierson@det.amedd.army.mil.

Animal Care & Use Review Office

ACURO

"The Animal Care and Use Review Office (ACURO) is the best kept secret in RCQ," is a description provided by Ms. Kathleen Dennis, ACURO, administrative.

ACURO's mission is to ensure that animal care and use within the United States Army Medical Research and Materiel Command (USAMRMC) intramural and extramural activities are conducted ethically and humanely in accordance with Federal and Department of Defense (DOD) regulations and guidelines. This office was established in 1990. In 1999, it was expanded to include oversight of the Defense Advanced Research Projects Agency's (DARPA) extramural research proposals.

The Animal Care Use and Review Branch
(From Left to Right) Back Row: COL Stephen Denny, Jack Fitzsimmons, Barbara Stone
Front Row: Kathleen Dennis, Lisa Fucci-Baker, Joyce O'Brien

The Director of ACURO is COL Stephen L. Denny, VC, who joined RCQ in mid-July, succeeding COL Nathaniel Powell as he retired from the Army. Prior to him arriving to RCQ, COL Denny served as Commander of the North Atlantic Regional Veterinary Command in Washington, DC and as the Commander at the Western Regional Veterinary Command in Fort Lewis, WA. The ACURO team welcomes COL Denny to RCQ and anticipates a very productive future for this branch under his guidance.

Long time veteran to this team is Ms. Joyce O'Brien, the Animal Care and Use Review Specialist. She is accountable for the review of virtually all animal use proposals. Joyce has been with the office since its inception in 1990.

Ms. Barbara Stone is responsible for annually collecting information from all active awards for the Congressionally mandated Animal Use Report. She also provides invaluable assistance wherever it is needed.

Ms. Kathleen Dennis is the primary Administrative Assistant, one out of two, within ACURO. She would like to encourage you to call upon her with any administrative questions, especially those concerning the status of animal use proposals.

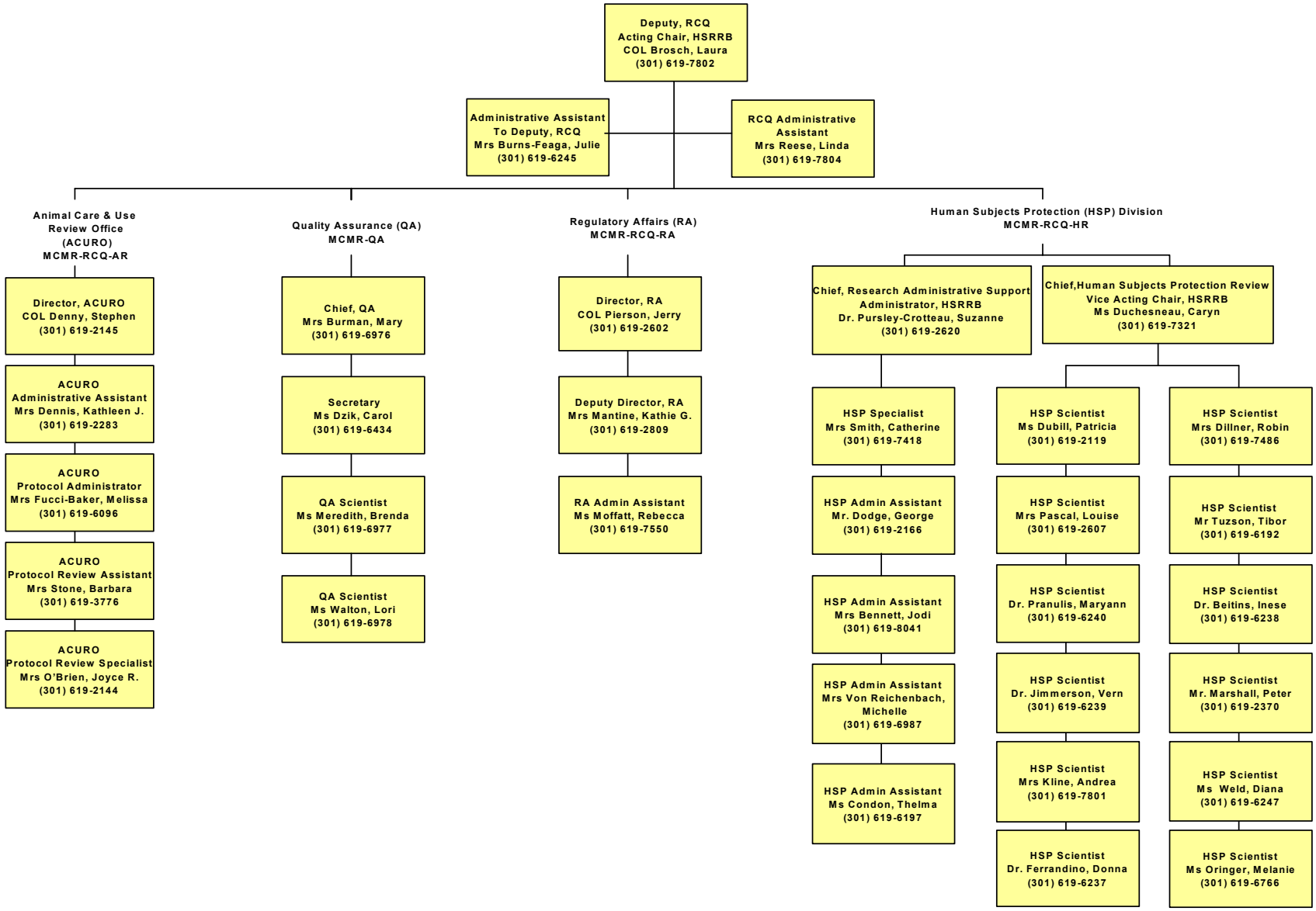
Ms. Lisa Fucci-Baker is the second Administrative Assistant within the division. However, her primary duty is to manage the DARPA proposals. If you have any questions about DARPA, contact Lisa, she's the expert.

Lastly, Mr. John Fitzsimmons is the ACURO Student Assistant and is also known as "Jack-of-all-trades." Jack is literally and figuratively ACURO's right-hand. Whether assisting with the collection of data for the animal use report, moving files or updating databases, Jack does it all — while maintaining a student status pursing his Master's degree.

In an effort to meet your specific needs, ACURO welcomes any questions, feedback or suggestions from their customers on areas that are in need of clarification. This branch is also in search of ways that they can effectively communicate to the public. Any concerns, requests or suggestions should be sent to COL Stephen Denny at Stephen.Denny@det.amedd.army.mil.

As Ms. O'Brien would and often does say, "We're from the Government — we're here to help!"

RCQ ORGANIZATION & TELEPHONE CHART



Note Part-time student office assistants include Ms. Maya Laws (QA), Ms. Kelly Ashley (HSP), Ms. Jessica Banks (HSP), Micki Garey (RA), Mr. Jack Fitzsimmons (ACURO), and Ms. Shannon Lertora (RCQ).

The Effect of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule on USAMRMC Research

Background.

The HIPAA Privacy Rule (often referred to only as "HIPAA") is a federal regulation developed by the Department of Health and Human Services that restricts the use and disclosure of identifiable health information (for example, a medical record with a person's name and social security number on it). The intent of HIPAA is to give people more control over their health information. HIPAA was finalized in August 2002. The DOD implemented HIPAA by regulation dated January 2003.

Covered entities must comply with HIPAA by April 14, 2003.

It is important to note that HIPAA applies only to organizations that are "covered" entities. A covered entity is a health plan, a health care clearinghouse (e.g., a billing service or community health information system), or a health care provider that transmits information electronically in connection with certain administrative and financial transactions (e.g., transactions about health care claim status, or eligibility for health plan coverage). Covered entities must comply with HIPAA by April 14, 2003.

USAMRMC is not a health plan, or a health care clearinghouse. USAMRMC laboratories and personnel do act as health care providers in the course of conducting research. However, USAMRMC health care providers do not engage in the transactions necessary for covered entities, with the exception of USAISR and USAMRIID. Therefore, only USAISR and USAMRIID are covered components within USAMRMC. This means that USAMRMC is a "hybrid" entity under HIPAA (an entity that has both covered and non-covered components). Only the covered components of a hybrid entity must comply with HIPAA.

Effects of HIPAA on Research.

All research must continue to comply with the Common Rule and its informed consent requirements, FDA regulations as applicable, and other DOD and DA regulations, whether or not the research is conducted by a HIPAA covered component. USAISR and USAMRIID, because they are covered, must also take additional steps to comply with HIPAA when conducting research.

HIPAA requires covered entities to obtain a signed and dated "authorization" from an individual to use or disclose an individual's health information in research. This authorization is a written document that can be part of the informed consent form, or it can be a separate document. It has to include a number of elements, for example a description of the health information, who may use or disclose the information, who will receive it, and the purpose of the use. An authorization is not needed if the information is not identifiable (or has only certain identifiers), the use or disclosure of the information is preparatory to research (for example, to design a research study), or the information is about decedents. In addition, an Institutional Review Board (IRB) can waive the authorization requirement if the use or disclosure of information involves only a minimal risk to a person's privacy, and it is not feasible to obtain an authorization from the research subjects. Individuals have a right to revoke their authorizations in writing.

HIPAA requires covered entities to obtain a signed and dated "authorization" from an individual to use or disclose an individual's health information in research.

USAMRMC also funds research that is conducted by universities or other research laboratories. Some of these research organizations are covered entities under HIPAA. Therefore, when reviewing these extramural research protocols, USAMRMC must be aware of the HIPAA status of the research organization, and the steps that the organization has taken to comply with HIPAA, if needed.

Finally, even if a given USAMRMC component is not covered, it may be receiving health information from a covered entity or component. The covered entity or component can only release this information if it has complied with HIPAA. Therefore, all components within USAMRMC, including the non-covered components, must consider how and from whom they receive health information, and must take steps to ensure that the entities providing that information are doing so in compliance with HIPAA. For questions regarding HIPAA contact Stephen Maleson at Stephen.Maleson@det.amedd.army.mil.

Submitted by Stephen E. Maleson,
Attorney/Advisor of USAMRMC-Judge Advocate General

USAMRMC LICENSURE, CREDENTIALING AND PRIVILEGING (LCP) PROGRAM

The Quality Assurance Branch within RCQ manages the Licensure, Credentialing and Privileging (LCP) Program for the United States Army Medical Research and Materiel Command (USAMRMC). This program focuses on medical readiness of healthcare personnel assigned to USAMRMC, specifically the assigned physicians.

USAMRMC currently has 107 assigned Army physicians, all possessing medical licenses as well as having their LCP data entered in the Centralized, Credentialing Quality Assurance System (CCQAS). These statistics resulted in 100% compliance as determined by U.S. Army Medical Command (MEDCOM) in Mar 03.

Statistics resulted in 100% compliance according to MEDCOM.

On 29 May 2003 and 4 June 2003, Brenda Meredith, the Command's Licensure, Credentialing and Privileging point of contact (POC), presented global LCP training to the LCP POCs of MRMC's major subordinate commands (MSC). The Commander of the respective laboratory/Institute appoints the LCP POCs. The purpose of the training was to integrate the MRMC MSC LCP POC into the management and maintenance of the Command LCP Program.

Furthermore, the LCP training covered Command Policy 2003-01, USAMRMC Licensure, Credentialing and Privileging Policy. This policy describes and elaborates on the requirements to ensure that USAMRMC Healthcare Personnel remain compliant with the LCP requirements as delineated in AR 40-68, Quality Assurance Administration.

In the near future, Brenda Meredith will be training each MSC LCP POC, individually, on the use of the Tri-Service Credentialing Database, CCQAS. For questions regarding CCQAS contact Brenda Meredith at Brenda.Meredith@det.amedd.army.mil.

COMING SOON!!

PRIM&R AND ARENA 2003 ANNUAL IRB CONFERENCE

Mark your calendars! Public Responsibility in Medicine and Research (PRIM&R) and the Applied Research Ethics National Association (ARENA) will be holding their 2003 Annual IRB Conference and related programs on 4-7 December 2003 at the Marriott Wardman Hotel, Washington, DC.

The conference will encompass the latest information on legal and ethical developments in the field of human subjects research, new strategies for running effective human subjects research programs and over 90 workshops on cutting issues such as HIPAA, Informed Consent, International Research and more.

This conference is intended for IRB members, administrators, and chairs; institutional officials; researchers and research staff: federal officials; industry and biotechnology representatives; patient advocates and representatives of voluntary health organizations; attorneys; and others interested in regulatory compliance.

Registration information is available online at www.primr.org or by calling 617-423-4112. Register early, space is limited!

RCQ REVIEW

Office of Regulatory Compliance & Quality
504 Scott Street
Fort Detrick, MD 21702

Phone: 301-619-6977
DSN: 343-6977
Fax: 301-619-4164
Email: Brenda.Meredith@det.amedd.army.mil

Managing Editor: Brenda Meredith
Co Editor: Shannon Lertora
Staff: Maya Laws

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Visit us online:
http://mrmc.detrick.army.mil

SHARE YOUR LESSONS LEARNED

What does "Lessons Learned" mean? It most often means learning by that most memorable and painful of teachers - Experience.

The USAMRMC RCQ Lessons Learned Program promotes the sharing of knowledge across the USAMRMC complex with specific emphasis on lessons learned relevant to Human Subjects Protection, Quality Assurance and Regulatory Compliance in general. The result of sharing lessons learned are improved efficiencies and effectiveness, reduced risk and waste, as well as acceleration of remediation project closure.

The benefits of information sharing via the USAMRMC RCQ Lessons Learned Program include:

- Improved Safety
- Enhanced Cost Effectiveness
- Greater Efficiency
- Better Operational Results
- Fewer Repeat Mistakes

Share your stories, experiences and best practices with us and we will publish it in our quarterly newsletter. Email your lessons learned to Brenda.Meredith@det.amedd.army.mil.

HELPFUL LINKS

• USAMRMC Homepage	http://mrmc.detrick.army.mil
• Public Responsibility in Medicine and Research	http://www.primr.org/
• Congressionally Directed Medical Research Programs	http://cdmrp.army.mil/
• World Medical Association	http://www.wma.net/e/policy/b3.htm
• International Conference on Harmonisation	http://www.ich.org/
• Code of Federal Regulations	http://www.access.gpo.gov/nara/cfr/cfr-table-search.html
• Army Publishing Directorate	http://www.usapa.army.mil/
• MEDCOM Quality Management Office	http://www.qmo.amedd.army.mil/home.htm
• Fort Detrick Homepage	http://www.detrick.army.mil/index.cfm
• Food and Drug Administration	http://www.fda.gov/
• Office for Human Research Protections	http://ohrp.osophs.dhhs.gov/